DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 5 2002

Constance A. Finch, Dr. P.H.
Director Regulatory Affairs
Becton Dickinson and Company
1 Loveton Circle
Sparks, Maryland 21152-0999

Re: Docket No. 98N-0337
Comment No. APP17

Dear Dr. Finch:

This letter is in response to your company's Application for Exemption dated July 6, 2001, requesting several exemptions from the labeling requirements for over-the-counter (OTC) drug products (21 CFR 201.66) for the Becton Dickinson (BD) BACTEC Blood Culture Procedural Tray, a convenience kit used to collect samples and culture organisms from blood. The convenience kit contains, among other items, a 0.75-percent povidone iodine swab stick and two 70-percent isopropyl alcohol prep pads. The basis for this request is that BD receives these products in bulk cases containing thousands of individual unit packages bearing labeling that does not comply with 21 CFR 201.66 and then repackages them in the kits.

You requested an exemption from the OTC format and content requirements in § 201.66(c) and (d) for the outside package of the convenience kit. In addition, you requested an exemption from the format requirements in § 201.66(d) and the content requirements in § 201.66(c)(1) through (c)(9) for the unit packages of the swab stick and alcohol prep pad.

You stated that this exemption request is reasonable for the following reasons: 1) Individuals using these convenience kits are licensed healthcare professionals who are aware of the procedures for safe use of the drug products in the kits, 2) the likelihood of consumer use of the convenience kits is extremely low, 3) 21 CFR 201.66 does not apply to convenience kits because they are not addressed by the regulation, and 4) the kits can be safely used as labeled because the purchaser of these products is provided with a Material Safety Data Sheet (MSDS) that

contains more extensive safety information for povidone iodine and isopropyl alcohol than that required by 21 CFR 201.66.

Regarding the requirement that the convenience kit contain the "Drug Facts" label specified in 21 CFR 201.66, you stated that this would require additional extensive labeling specific to the drug components of the kit. You also suggested that requiring each drug component unit package to contain the "Drug Facts" label is impractical because the product is not provided with such a label and would have to be repackaged or "overlabeled" to comply with the regulation. In addition, you stated that this would add considerably to the cost of producing the product, without improving the information provided to the intended user.

We have completed our review of the request and have the following comments:

Although the convenience kit is intended for professional use, the labeling requirements in 21 CFR 201.66 do not distinguish between OTC drug products marketed to consumers and those marketed to healthcare professionals. Therefore, marketing of OTC drug products intended for professional use does not preclude the need for labeling as required by 21 CFR 201.66.

The agency believes that convenience kit packages containing OTC drug products must bear the "Drug Facts" labeling specific to the OTC drug components of the kit. Because these convenience kits are used every day by individuals with varying experience, these products should contain complete information for safe and proper use. Therefore, the convenience kit package labeling will be required to comply with 21 CFR 201.66 according to the timeline established for the OTC drug products included in the kit.

Although the MSDS that you recently submitted is provided to the purchasing agent and may be available in an MSDS manual for use in emergencies, it is not available at the point of use and does not constitute OTC drug product labeling.

The OTC drug unit packages will not be required to comply with 21 CFR 201.66, provided that the kit package label

includes "Drug Facts" labeling specific to the drug products included in the kit.

The povidone iodine swab stick packaged in the kit is subject to regulation as an OTC drug product. The current labeling for the kit and the unit package does not contain the complete labeling that would be required when the final rule is issued for these specific products. At this time, the agency recommends using OTC drug labeling that complies with the healthcare antiseptic tentative final monograph (56 FR 48302). The timeline for implementation of "Drug Facts" labeling for these products will be specified in the healthcare antiseptic final monograph. As the monograph has not been finalized as of May 16, 2002, the product must comply as of the first major labeling revision after this date, the date stated in the final monograph, or by May 16, 2005, whichever occurs first (65 FR 38191 at 38193).

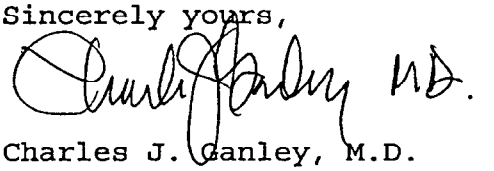
Based on the kit's directions for use, it is unclear if the isopropyl alcohol prep pads are intended to be used as OTC drugs. Although the purpose of the alcohol pads appears to be only to clean the vials and to remove the povidone iodine from the collection site, the unit package for this component of the product contains drug labeling. If the alcohol pads are intended for use as an OTC drug product, i.e., as a skin disinfectant, the kit package will need to bear "Drug Facts" labeling specific to this use. However, if the alcohol pads are only intended for cleansing purposes (not for use on human skin), they should be labeled accordingly.

Your application for exemption fails to provide evidence that the kit package cannot accommodate the labeling requirements for the drug component(s) as specified in 21 CFR 201.66. Other kits, such as OTC first aid kits that contain drug components, are also subject to the labeling requirements in 21 CFR 201.66. Further, your application fails to demonstrate a need for the requested exemption other than the inconvenience and additional costs involved if your company is required to relabel the kit packaging to comply with this regulation.

As the agency has previously indicated, it is unlikely to grant exemptions based solely on financial considerations. The final rule has already addressed the fact that there will be cost increases to some manufacturers to comply with the new labeling requirements.

Therefore, for the reasons stated above, your request for exemption from 21 CFR 201.66 for the individual kit package labeling is denied. As stated above, the unit packages for OTC drug products included in these kits will not be required to comply with 21 CFR 201.66, provided that the kit outer package labeling includes "Drug Facts" labeling specific to these drug products. Also, as noted above, "Drug Facts" labeling is not required at this time, but will need to be implemented in the future. If you have any questions, please contact Robert Sherman of my staff at 301-827-2222.

Sincerely yours,



Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337 (OTC LABELING FINAL RULE)

TO: Dockets Management Branch, HFA-305

☑ The attached material should be placed on public display under the above referenced Docket No.

☑ This material should be cross-referenced to Comment Nos ANS17 AND APP17

Charles J. Ganley, M.D.

Attachment